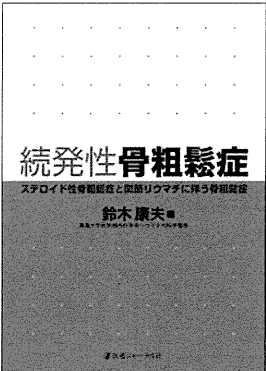


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続発性骨粗鬆症

～ステロイド性骨粗鬆症と 関節リウマチに伴う骨粗鬆症～

東海大学医学部内科学系リウマチ内科学教授 鈴木 康夫 編

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◎年齢、性別を問わず、特定の原因により発症する続発性骨粗鬆症。それによる骨折は、大きな社会問題となっている。

◎本書では、その疫学や病態・予防治療に関して、特に新しい知見の多いステロイド性骨粗鬆症と関節リウマチに伴う骨粗鬆症の最新情報をまとめた。

◎有効な薬剤が開発されつつある現在、疾患に対する理解と治療にぜひ役立てていただきたい一冊。

株式会社 医薬ジャーナル社 〒541-0047 大阪市中央区淡路町3丁目1番5号・淡路町ビル21 電話 06(6202)7280(代) FAX 06(6202)5295 (振替番号) 00910-1-33353
〒101-0061 東京都千代田区三崎町3丁目3番1号・TKiビル 電話 03(3265)7681(代) FAX 03(3265)8369
<http://www.iyaku-j.com/> 書籍・雑誌バックナンバー検索, ご注文などはインターネットホームページからが便利です。

Cross-cultural adaptation and validation of the Japanese Knee Injury and Osteoarthritis Outcome Score (KOOS)

Norimasa Nakamura · Ryohei Takeuchi ·
Takeshi Sawaguchi · Hiroyuki Ishikawa ·
Tomoyuki Saito · Sabine Goldhahn

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Abstract

Background In Japan, only few cross-culturally adapted, internationally used orthopaedic patient self-assessed outcome scores are available. In addition, the high incidence of knee osteoarthritis (OA) suggests the need for validated outcome measures such as the widely used Knee Injury and Osteoarthritis Outcome Score (KOOS) for Japanese populations. The purpose of this study was to provide a cross-culturally adapted and validated KOOS questionnaire for further use in national and international clinical projects involving Japanese patients.

The Japanese version of the KOOS will be published with a Japanese version of the abstract in the Journal of the Japanese Orthopaedic Association.

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N. Nakamura
Department of Rehabilitation Science, Osaka Health Science
University, 1-9-27 Tenma, Kita-ku, Osaka 530-0043, Japan

R. Takeuchi · H. Ishikawa · T. Saito
Department of Orthopaedic Surgery, Yokohama City University
School of Medicine, 3-9, Fukuura, Kanazawa-ku,
Yokohama 236-0004, Japan

T. Sawaguchi
Department of Orthopaedics and Joint Reconstructive Surgery,
Toyama Municipal Hospital, 2-1, Imaizumi-Hokubu,
Toyama 939-8511, Japan

S. Goldhahn (✉)
AO Clinical Investigation and Documentation,
Stettbachstrasse 6, 8600 Duebendorf, Switzerland
e-mail: sabine.goldhahn@aofoundation.org

Methods The Japanese KOOS was developed according to the standard cross-cultural adaptation guidelines. For validation, the KOOS was tested on 58 patients diagnosed with OA. Reliability was tested using the intraclass correlation coefficient (ICC). Internal consistency or homogeneity was assessed using Cronbach's alpha. Construct validity was evaluated by quantifying the correlation between the KOOS and the Japanese OKS and SF-36 questionnaires with Spearman's correlation coefficients.

Results No major difficulties were encountered during the translation and pre-testing stages. All five KOOS subscales showed adequate reproducibility with ICC values greater than 0.85, high internal consistency with Cronbach's alpha values around 0.90, and high Spearman's coefficients over 0.50 signifying good correlation between the KOOS subscales and the OKS as well as the majority of the established subscales of the SF-36. No floor and ceiling effects were observed for the five subscales.

Conclusions Our validated Japanese KOOS is a reliable and stable outcomes measure that provides a valuable basis for national and international clinical projects focusing on patient-based assessments in knee OA.

Introduction

The goal of clinical treatment is to improve the health condition of the patient. This has especially been recognized over the past 2 decades by the increased availability of literature concerned with creating and validating patient self-assessed outcome measurements such as health-related quality of life (HRQoL) questionnaires or disease-specific function measures. In order to apply these survey measures to patient populations from different countries, the linguistic, behavioural and cultural peculiarities have to be

respected; this demands a careful process of cross-cultural adaptation according to published guidelines [1, 2].

Although Japanese is the first language of around 130 million people worldwide and the incidence of knee complaints such as osteoarthritis (OA) is higher in Japan than in any other country [3, 4], very few efforts have been made to cross-culturally adapt internationally used orthopaedic patient self-assessed outcome scores into Japanese. For the knee, there is no validated Japanese version that has been published except for the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) that also assesses OA of the hip [5]. Consequently, the function and health-related quality of life of Japanese knee patients are often subjectively assessed by the treating orthopaedic surgeon or determined using the Japanese Knee Osteoarthritis Measure [6], which is solely used in Japan.

To integrate Japanese knee patient self-assessments into international clinical projects and facilitate comparisons of treatment results, cross-cultural adaptation of the widely used Knee Injury and Osteoarthritis Outcome Score (KOOS) was the primary goal of this study.

Materials and methods

Cross-cultural adaptation

The cross-cultural adaptation of the KOOS into Japanese was performed according to published guidelines [1, 2]. Briefly, the English version of the KOOS was separately translated by three native Japanese bilingual translators (two with medical backgrounds and one linguist). After uniform agreement was reached among the three forward translators, a common Japanese translation was available. This version was back-translated by two bilingual non-medical, professional translators with the source language as their mother tongue, who were blinded to the original English version. A pre-final consensus version that required only minor amendments was reached by the collective of health and language professionals, and forward and back translators. This version was sent to and approved by the inventor of the KOOS, and then tested for comprehensibility in 51 subjects aged between 18 and 85 years (Supplementary Material, Japanese KOOS).

Validation study

Patients and data collection

Patients were eligible for recruitment at the outpatient departments of two Japanese orthopaedic hospitals if they were diagnosed with knee OA and provided informed consent to participate in this study. Fifty-eight patients

(87.9% women) with a mean age of 68.9 ± 9.4 years were included in our series. Knee OA was graded according to the Kellgren-Lawrence classification [7]: 16 cases had grade 1 OA (27.59%), 16 had grade 2 OA (27.59%), 15 had Grade 3 OA (25.86%) and 11 had grade 4 OA (18.97%).

Each patient received a set of questionnaires for immediate completion during their medical examination. For reliability testing, patients from the first hospital received the series of questionnaires again at a second follow-up consultation, which occurred 7 days after the first appointment. For patients from the second hospital, the set of questionnaires was mailed to them a couple of days later; they were instructed to complete the surveys again at home 7 days after the initial consultation and return them.

Instruments

The KOOS (<http://www.koos.nu/>) is a 42-item joint-specific measure that was developed to assess short- and long-term outcomes in patients with knee injuries, as they are often at risk of developing knee OA [8]. It consists of five subscales that are scored separately from 0 (extreme problems) to 100 (no problems): pain, symptoms, activities of daily living (ADL); sport and recreation function, and knee-related quality of life. This instrument was developed as an extension of the WOMAC [9, 10] and includes the WOMAC in its original form plus additional items [8] considered in the pain subsection. Thus, the WOMAC can be separately calculated from the KOOS. After its initial validation in Swedish with subjects undergoing knee arthroscopy and in American English with subjects undergoing surgical reconstruction of the anterior cruciate ligament, the KOOS has been further validated in several other languages [11–16]. This measure has been used for several medical conditions and orthopaedic treatments including OA, total knee replacement for OA [17], drug treatment for OA [18], high tibial osteotomy [19], patellofemoral OA in meniscectomized patients [20] among others.

The Oxford 12-item Knee Score (OKS) consists of 12 items that address the perception of pain and function based on the categories of response of a 5-point Likert scale [21]. Thus, each item is scored from 1 to 5 (i.e. least to most difficult or severe) and combined to produce a single score ranging from 12 (best) to 60 (worst) points. Although it was recommended to score the five answers from 0 to 4 (resulting in a total score of 48 points) [22], the original 1- to 5-point scoring, cross-culturally adapted and validated Japanese version [23], was used for this validation study.

The Short Form-36 (SF-36) Health Survey is the most widely used questionnaire on HRQoL. It measures health on eight multi-item dimensions covering functional status, well-being and overall evaluation of health (i.e. physical functioning, role-physical, bodily pain, general health,

vitality, social functioning, role-emotional, mental health). In this validation study, the SF-36v2 (4-week recall) was used. Patients were asked to rate their responses on a 3-, 5- or 6-point Likert scale. For each dimension, item scores are calculated, summed and transformed to a scale ranging from 9 (worst health) to 100 (best health) [24].

Psychometric characteristics of the Japanese KOOS

The reproducibility (test-retest reliability) of the KOOS was assessed by calculating the Intraclass Correlation Coefficient (ICC). The ICC ranges from 0.00 (no agreement) to 1.00 (perfect agreement) and describes how the same test results are obtained for repeated assessments when no real change is expected for a subject within the assessment period. For each item of the KOOS and for the KOOS subscores, the ICC was calculated between the responses of the first and the second questionnaire (i.e. test and retest). In cases where one or two questionnaire responses were missing, these were replaced by the mean of the completed subscale responses. In cases with three or more missing responses, the subscale was not calculated for the patient.

Internal consistency or homogeneity of the KOOS was assessed using Cronbach's alpha. This estimation can vary between 0.00 (no correlation) and 1.00 (perfect correlation), where a good correlation among the items (between 0.70 and 0.90) indicates strong internal consistency; higher values may demonstrate a redundancy of items [25].

Construct validity measures the extent to which a score measures what it is supposed to measure. Correlations between the translated KOOS and the SF-36, and Japanese OKS were tested using Spearman's correlation coefficient. Since the KOOS was designed to measure physical health, we hypothesized the following four strong convergent correlations of greater than 0.50 between the KOOS subscales and the OKS, and between the KOOS subscales and the physical components of the SF-36, i.e. physical functioning, role-physical and bodily pain. Three hypotheses were generated where we expected weak to moderate correlations of less than or equal to 0.50, indicating divergent validity between all KOOS subscales and SF-36 mental components, i.e. social functioning, role-emotional and mental health [26].

To assess floor and ceiling effects of the Japanese KOOS, the proportion of answer frequencies with the worst (4) and best possible (0) value on the 5-point Likert scale was calculated for each of the 42 survey items as well as for the five subscales with the lowest (i.e. worst) and highest (i.e. best) score. Scores with floor or ceiling effects may not detect improvements or deteriorations in the patients as they are already at the lower or upper end of the scale. When more than 15% of the participants obtained the highest or lowest score, an effect was noted [27].

Statistical analysis

All analyses were performed using Intercooled Stata version 11 (StataCorp LP, College Station, TX). The scores were reported as mean values \pm standard deviation, and $P \leq 0.05$ was considered significant.

Results

Translation and cross-cultural adaptation

For the cross-culturally adapted KOOS, some Japanese words normally expressed in Kanji—the Chinese characters used in the Japanese writing system—were changed to the Japanese characters of the Kana syllabary Hiragana in order to be more easily read by patients of all education levels. Overall, no major problems were reported from the three forward translators. In the agreement meeting, items S2 (Do you feel grinding, hear clicking or any other type of noise when your knee moves?), S6 (How severe is your knee joint stiffness after first wakening in the morning?) and S7 (How severe is your knee stiffness after sitting, lying, or resting later in the day?) were topics of discussion as no completely identical phrase could be identified in Japanese. For item A10 (Rising from bed), the Japanese Kana for Western style beds were used instead of the Kanji for the typical Japanese futon. Major discussions were raised for item A12 (Lying in bed [turning over, maintaining knee position]) as no Japanese expression could be identified for an appropriate expression of “maintaining knee position”; this part of the question was replaced by the equivalent Japanese translation for “and others”. Item A15 (Getting on/off toilet) was another point of discussion; the expression of “Western style toilet” was used instead of the phrase for typical Japanese toilets. No further issues were observed during the back translation and pretesting phase for comprehensibility of the cross-cultural adaptation.

Reliability and internal consistency

Of the 58 included patients, 53 (91.38%) completed the entire questionnaire at the first and second distribution, respectively. For each of five subjects at the first distribution and four subjects at the second distribution, only one item was missing; for one subject at the second distribution, two answers were missing. For calculation of the five subscores, these missing items were imputed with the mean of the completed subscale response. Two of the respondents had a missing questionnaire item at both test assessments. The mean test-retest data for the five subscales are shown in Table 1. The ICC values were all over 0.85, indicating adequate reproducibility of the KOOS.

Table 1 Reliability data for the five Japanese Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales

Subscore ^a	Test (T1), <i>n</i> = 58				Retest (T2), <i>n</i> = 58				ICC	95% CI (ICC)	CA
	Min	Max	Mean	SD	Min	Max	Mean	SD			
Pain	19.44	100 (3%)	67.09	21.11	19.44	100.00	67.68	20.63	0.89	0.82–0.93	0.90
Symptoms	25.00	100 (5%)	71.38	18.97	17.86	100.00	70.81	18.29	0.88	0.80–0.93	0.90
ADL	25.00	100 (5%)	75.84	18.91	30.89	98.53	76.00	18.78	0.88	0.80–0.93	0.89
Sport/recreation	0 (10%)	100 (2%)	45.91	32.95	0	95.00	49.31	32.18	0.90	0.83–0.94	0.90
QOL	0 (2%)	100 (3%)	49.35	25.77	0	100.00	53.16	26.64	0.86	0.77–0.92	0.89

Percentages in parentheses represent the proportion of study patients with the lowest or highest possible score for the nominated KOOS subscore, and provide information regarding floor and ceiling effects

SD standard deviation, *ICC* intraclass correlation coefficient, *95% CI* 95% confidence interval, *CA* Cronbach's alpha estimation of internal consistency, *ADL* activities of daily living, *QoL* quality of life

^a Each subscore contains a number of the 42 KOOS items (see Appendix). The total score of 100 points, best score; 0, worst score

Table 2 Construct validity

Reference score	Mean score \pm SD	KOOS pain	KOOS symptoms	KOOS ADL	KOOS Sport/Rec	KOOS QOL
SF-36 (physical function)	62.74 \pm 21.62	<i>0.68**</i>	<i>0.71**</i>	<i>0.74**</i>	<i>0.72**</i>	<i>0.60**</i>
SF-36 (role-physical)	60.24 \pm 28.79	<i>0.49**</i>	<i>0.47**</i>	<i>0.62**</i>	<i>0.63**</i>	<i>0.62**</i>
SF-36 (bodily pain)	47.41 \pm 21.64	<i>0.67**</i>	<i>0.61**</i>	<i>0.74**</i>	<i>0.67**</i>	<i>0.67**</i>
SF-36 (general health)	56.81 \pm 17.43	<i>0.35**</i>	<i>0.41**</i>	<i>0.28*</i>	<i>0.31*</i>	<i>0.21</i>
SF-36 (vitality)	56.72 \pm 19.30	<i>0.31*</i>	<i>0.30*</i>	<i>0.37**</i>	<i>0.30*</i>	<i>0.31*</i>
SF-36 (social function)	71.77 \pm 23.60	<i>0.33*</i>	<i>0.32*</i>	<i>0.28*</i>	<i>0.28*</i>	<i>0.34**</i>
SF-36 (role-emotional)	64.18 \pm 30.50	<i>0.37**</i>	<i>0.35**</i>	<i>0.59**</i>	<i>0.50**</i>	<i>0.46**</i>
SF-36 (mental health)	64.25 \pm 22.40	<i>0.36**</i>	<i>0.30*</i>	<i>0.31*</i>	<i>0.34*</i>	<i>0.34*</i>
Oxford Knee Score	27.24 \pm 9.69	<i>-0.80**</i>	<i>-0.78**</i>	<i>-0.85**</i>	<i>-0.79**</i>	<i>-0.74**</i>

Spearman's correlation coefficients (r_s) when comparing the five KOOS subscales to the SF-36 and Oxford Knee Score

Italicized numbers indicate that a priori hypotheses were supported

SF-36 Short Form-36 Health Survey, *SD* standard deviation, *ADL* activities of daily living, *Sport/Rec* sport/recreation, *QOL* quality of life

* Significant correlation at the 0.05 level (2-tailed)

** Significant correlation at the 0.01 level (2-tailed)

Cronbach's alpha for the individual questionnaire subscales ranged from 0.89 to 0.90, which suggests a high level of internal consistency.

Based on the individual questionnaire items, item P8 (What amount of pain have you experienced the last week during sitting or lying?) showed the lowest reliability with an ICC value of 0.45 (95% CI 0.21–0.63); the highest ICC value of 0.90 was calculated for item P3, i.e. Straightening the knee fully (Appendix).

Validity

As hypothesized, there were strong correlations when comparing all KOOS subscales with the OKS and the SF-36 physical function, role-physical and bodily pain score elements except for KOOS pain and symptoms versus the SF-36 role-physical subscore ($r_s = 0.49$ and 0.47 , respectively, $P < 0.01$) (Table 2). Hypothesized divergent

construct validity (none to weak/moderate correlation) was found between all KOOS subscales and the mental component equivalents of the SF-36 (i.e. social function, role-emotional, mental health) except for the KOOS ADL and sport/recreation subscales versus the SF-36 role-emotional component (i.e. higher than expected correlations of 0.59 and 0.50 were calculated, respectively). The remaining two SF-36 elements, which assess general health and vitality, also showed no, weak or only moderate correlations with all five KOOS subscales (Table 2).

Floor and ceiling effects

Generally, there were no considerable floor or ceiling effects for the five KOOS subscales (Table 1). For 12 of the individual KOOS items (Appendix), a floor effect was observed with 38, 32 and 31% of the patients reporting the worst score for items Q1 (How often are you aware of your

knee problems?), SP3 (Jumping) and P1 (How often do you experience knee pain?), respectively. Considerable ceiling effects in the single items were observed for all items except items S7 (How severe is your knee stiffness after sitting, lying or resting later in the day?), P1 (How often do you experience knee pain?), P2 (Twisting/pivoting on your knee), SP2 (Running), SP3 (Jumping), Q1 (How often are you aware of your knee problem?), Q3 (How much are you troubled with lack of confidence in your knee?) and Q4 (In general, how much difficulty do you have with your knee?) (Appendix). The highest ceiling effect was found for items A14 (Sitting) and A15 (Getting on/off toilet), with 81 and 76% of the patients reporting no difficulties for the respective activities.

Discussion

Compared to other populations, the number of patients with knee OA is remarkably high in Japan, leading to a major impact on the public health care system. Among the diseases requiring support in ADL, knee OA is ranked as second by the National Livelihood Survey of the Ministry of Health, Labour and Welfare in Japan [4, 28]. In conjunction with an aging society, there is a strong need for measurement tools to assess the impact of knee OA—related to a former knee injury or not—on the life of the patient, and evaluate the outcome from the patient's perspective after specific treatments. Due to the continuing lack of available Japanese patient self-assessment tools for evaluating knee complaints, the goal of this study was to cross-culturally adapt and validate one of the most widely used patient self-rating knee outcome instruments, the KOOS. The Japanese KOOS showed comparable reliability, internal consistency and construct validity to that of the original KOOS as well as other language versions [8, 12–16].

With respect to the peculiarities of the Japanese language, where the same words can be expressed using three different types of writing and the same syllables can be expressed with different Kanji characters, it was agreed that three instead of the officially recommended two forward translators should translate the 42 questionnaire items. Although there were some discussions in the agreement meeting between the three forward translators regarding certain phrases, these difficulties were resolved, and the overall results for reliability and validity indicate the satisfactory ability of the translated questionnaire to assess patient-rated outcomes associated with knee injury and OA.

As reported for the original KOOS and the German, Dutch, Portuguese, Persian, French, Singapore English and Chinese versions, good correlations for all five subscales and single items indicating good stability of the instrument

were also found for the Japanese KOOS. Only for item P8 (What amount of pain have you experienced the last week during sitting or lying?), the ICC value of 0.45 was the lowest calculated correlation of all the 42 individual items. One reason could be that pain is a very subjective perception that can vary even within a 7-day interval and can also depend on several factors such as the level of depression [29], the circadian rhythm [30] of an individual as well as others. Nevertheless, this explanation may not unequivocally explain our finding of a low correlation for pain experienced exclusively while sitting or lying.

Internal consistency was strong and not higher than 0.90 for all five subscales of our KOOS version, indicating that there is no redundancy in the items of the Japanese KOOS when used in patients with knee OA. In contrast to our results, higher CA values (>0.90) were reported for the ADL subscale of the KOOS in Persian, Portuguese, Dutch, French and Singapore English [11–13, 15, 16], and for the sports/recreation subscales of the Portuguese and Dutch versions [11, 15], suggesting that there may be some redundancy in the related questions of the original KOOS construct itself. A direct comparison of internal consistency with the English KOOS version is not possible because CA values were not reported in the original publication [8].

Although ceiling effects were observed for the majority of single items with few individual floor effects, this had no notable consequence on the relation of minimum and maximum scores of the five subscales. Age and gender factors of our study population are comparable to the Portuguese, French, Swedish and the Singapore English and Chinese versions, but not to the Persian series, which included younger patients with a larger proportion of males. A possible reason for the ceiling effects in the single items of our sample could be the influence of patients with mild (grade 1) OA (28%), who are likely to have fewer complaints compared to those with more severe forms of the disease. This conforms to the findings of the Dutch validation study [15], which also included patients with mild OA; ceiling effects had such a notable influence on three (pain, symptoms and ADL) of the five subscales. The floor effects for all items of the sports/recreation and three items of the QoL subscales in our sample are most likely due to the inclusion of cases with more severe OA who were no longer able to participate in sporting activities. Despite the reported floor effects for all single items in the sports/recreation subscale, their influence was not as pronounced on the overall sports/recreation subscale itself. Much higher floor effects in this subscale are reported from the Singapore English and Chinese versions [13]. Severe OA cases included in the Dutch questionnaire had a strong influence to the extent that floor effects of 38 and 15% were observed for the sport/recreation and QoL subscales, respectively.

Five of our seven proposed hypotheses regarding construct validity could be confirmed, which indicates the satisfactory validity of the Japanese questionnaire [27]. Only the correlations between KOOS ADL and sport/recreation with the SF-36 role-emotional component were higher than 0.50, and the correlations of SF-36 role-physical versus KOOS pain and KOOS symptoms subscales were lower than expected. A remarkably weaker correlation between the latter subscore comparison was also reported for the Persian (0.38 for pain and 0.15 for symptoms) and the Singapore English and Chinese (for pain, 0.23 each and for symptoms 0.21 and 0.18, respectively) versions. These adapted questionnaires had generally lower correlations between the KOOS subscales and all three physical domains of the SF-36.

Some limitations of our study include the small sample size of 58 patients, which may be considered too low for testing reliability and validity. Nonetheless, this number lies within the quality criteria outlined by Terwee et al. [27] that proposes a minimum requirement of at least 50 patients for satisfactorily evaluating health status measures. Although it is difficult to prove, the two different methods in which the second questionnaire was distributed in this study could have some influence on the reliability of this

patient-rated survey. Lastly, further research is needed to assess the responsiveness of the Japanese KOOS. As the presented work is part of a recently initiated 5-year study focusing on patients with OA, this psychometric aspect will be evaluated in the context of this larger project.

The currently validated Japanese KOOS is a reliable and stable outcomes measure that provides a valuable basis for all clinical studies looking specifically at patient opinion concerning their knee OA. It also provides a significant contribution to the ever-increasing trend of internationally used patient self-assessed scores in Asian languages.

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Conflict of interest The work of the study was supported by the AO Foundation and Synthes Japan. The authors did not receive any benefits from any commercial party related directly or indirectly to the subject of this article.

Appendix

See Table 3

Table 3 Reliability data for the individual 42 items of the Japanese Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire

Item number ^a	Test (T1)				Retest (T2)				ICC	95% CI (ICC)
	Min	Max	Mean	SD	Min	Max	Mean	SD		
1 (S1)	0 (47%)	4 (12%)	1.05	1.34	0	4	1.22	1.28	0.73	0.58–0.83
2 (S2)	0 (38%)	4 (9%)	1.14	1.22	0	4	1.07	1.14	0.70	0.54–0.81
3 (S3)	0 (60%)	4 (2%)	0.53	0.80	0	3	0.55	0.78	0.51	0.29–0.68
4 (S4)	0 (29%)	4 (9%)	1.19	1.16	0	4	1.03	1.15	0.54	0.34–0.70
5 (S5)	0 (22%)	4 (12%)	1.66	1.33	0	4	1.83	1.27	0.78	0.65–0.86
6 (S6)	0 (26%)	3	1.21	0.99	0	4	1.19	0.98	0.71	0.55–0.81
7 (S7)	0 (12%)	4 (2%)	1.24	0.82	0	3	1.28	0.85	0.61	0.41–0.75
8 (P1)	0 (10%)	4 (31%)	2.40	1.38	0	4	2.29	1.28	0.72	0.57–0.82
9 (P2)	0 (14%)	4 (9%)	1.60	1.14	0	4	1.61	1.08	0.84	0.74–0.90
10 (P3)	0 (34%)	4 (9%)	1.12	1.20	0	4	1.02	1.18	0.90	0.84–0.94
11 (P4)	0 (24%)	4 (9%)	1.66	1.30	0	4	1.71	1.38	0.77	0.65–0.86
12 (P5)	0 (42%)	3	0.90	0.94	0	3	0.91	0.90	0.69	0.52–0.80
13 (P6)	0 (17%)	4 (7%)	1.60	1.11	0	4	1.53	1.10	0.67	0.52–0.80
14 (P7)	0 (43%)	3	0.76	0.80	0	3	0.86	0.89	0.83	0.73–0.90
15 (P8)	0 (34%)	4 (3%)	0.95	0.95	0	3	0.95	0.83	0.45	0.21–0.63
16 (P9)	0 (40%)	4 (2%)	0.86	0.89	0	3	0.76	0.84	0.77	0.64–0.86
17 (A1)	0 (22%)	4 (7%)	1.62	1.24	0	4	1.53	1.14	0.78	0.65–0.86
18 (A2)	0 (21%)	4 (7%)	1.45	1.17	0	4	1.34	1.12	0.72	0.57–0.83
19 (A3)	0 (16%)	4 (2%)	1.41	0.96	0	4	1.37	0.98	0.72	0.56–0.82
20 (A4)	0 (35%)	3	0.88	0.84	0	3	0.86	0.98	0.74	0.60–0.84
21 (A5)	0 (29%)	4 (3%)	1.19	1.08	0	4	1.21	0.99	0.72	0.57–0.82
22 (A6)	0 (48%)	4 (3%)	0.81	0.98	0	3	0.71	0.88	0.72	0.57–0.83

Table 3 continued

Item number ^a	Test (T1)				Retest (T2)				ICC	95% CI (ICC)
	Min	Max	Mean	SD	Min	Max	Mean	SD		
23 (A7)	0 (29%)	4 (3%)	1.12	1.06	0	4	0.98	0.93	0.79	0.67–0.87
24 (A8)	0 (40%)	4 (5%)	1.05	1.18	0	4	0.98	1.15	0.78	0.62–0.85
25 (A9)	0 (52%)	3	0.74	0.93	0	3	0.84	0.93	0.82	0.72–0.89
26 (A10)	0 (50%)	3	0.67	0.78	0	3	0.79	0.87	0.74	0.60–0.84
27 (A11)	0 (52%)	3	0.67	0.80	0	3	0.83	0.92	0.76	0.62–0.85
28 (A12)	0 (53%)	3	0.69	0.86	0	3	0.70	0.89	0.72	0.57–0.83
29 (A13)	0 (45%)	4 (3%)	0.81	0.96	0	4	0.79	0.99	0.83	0.72–0.89
30 (A14)	0 (81%)	2	0.24	0.54	0	3	0.31	0.63	0.70	0.54–0.81
31 (A15)	0 (76%)	2	0.26	0.48	0	2	0.36	0.61	0.55	0.34–0.71
32 (A16)	0 (17%)	4 (21%)	1.88	1.43	0	4	1.76	1.20	0.80	0.68–0.88
33 (A17)	0 (50%)	4 (9%)	0.93	1.23	0	4	0.93	1.20	0.79	0.67–0.87
34 (SP1)	0 (19%)	4 (22%)	1.91	1.44	0	4	1.76	1.35	0.84	0.74–0.90
35 (SP2)	0 (7%)	4 (29%)	2.38	1.34	0	4	2.31	1.38	0.81	0.70–0.88
36 (SP3)	0 (11%)	4 (32%)	2.33	1.44	0	4	2.17	1.49	0.82	0.71–0.89
37 (SP4)	0 (16%)	4 (22%)	2.07	1.40	0	4	1.95	1.46	0.81	0.70–0.88
38 (SP5)	0 (21%)	4 (30%)	2.10	1.54	0	4	1.95	1.38	0.81	0.70–0.88
39 (Q1)	0 (5%)	4 (38%)	2.78	1.24	0	4	2.48	1.30	0.70	0.54–0.82
40 (Q2)	0 (26%)	4 (7%)	1.46	1.22	0	4	1.25	1.13	0.71	0.56–0.82
41 (Q3)	0 (10%)	4 (18%)	1.93	1.27	0	4	1.75	1.27	0.79	0.67–0.87
42 (Q4)	0 (7%)	4 (16%)	1.95	1.18	0	4	1.90	1.17	0.82	0.71–0.89

Percentages in parentheses represent the proportion of study patients with the lowest or highest possible score for the nominated KOOS item, and provide information regarding floor and ceiling effects

SD standard deviation, ICC intraclass correlation coefficient, 95% CI 95% confidence interval

^a Each item refers to the individual 42 questions of the KOOS survey; a single item score of 0 points, best score, and 4, worst score

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Radiographic improvement of damaged large joints in children with systemic juvenile idiopathic arthritis following tocilizumab treatment

Very few studies have reported radiographic improvement of damaged joints in patients with juvenile idiopathic arthritis (JIA) following treatment with biological response modifiers.¹ We previously reported the efficacy and safety of tocilizumab, an anti-interleukin 6 receptor monoclonal antibody, in patients with systemic-onset JIA.²⁻⁴ In the present study, we investigated remodelling characteristics of damaged large joints, especially weight-bearing joints, by radiographic examination following tocilizumab treatment for 5 years.

Seven patients (two female and five male) with systemic-onset JIA, receiving 8 mg/kg of tocilizumab intravenously every 2 weeks, were studied. Mean age at the start of tocilizumab treatment was 8.6 years (range 3.4–10.4 years) and the mean follow-up period was 56 months (range 55–57 months). The large joints (shoulders, elbows, hips, knees and ankles) were evaluated for joint space narrowing, cyst formation, erosion and localised growth abnormalities. The degree of large joint damage was evaluated radiographically employing a modified Larsen method.^{5,6} The grading scale ranges from 0 to 5 (0 = normal joint, 5 = mutilating changes) for each joint. Thus, the Larsen score for 10 large joints (bilateral shoulders, elbows, hips, knees, ankles) ranges from 0 to 50. To facilitate the assignment of Larsen scores, we compared each study patient's radiographs with those from a healthy child of the same bone age. In order to assess the joint space narrowing of the hand, the carpal length was measured by the Poznanski method.⁷ Radiographs were read by an experienced orthopaedist and a paediatric rheumatologist who had

Table 1 Baseline characteristics and response variables of patients

Case	Gender	Age at onset (years)	Age at TCZ (years)	F/U (months.)	Active joints		WBC (/ml)		CRP (mg/dl)		ESR (mm/h)		CHAQ		Larsen score		Poznanski score		Radiologic change (joints)		
					Before TCZ	After TCZ	Before TCZ	After TCZ	Before TCZ	After TCZ	Before TCZ	After TCZ	Before TCZ	After TCZ	Before TCZ	After TCZ	Before TCZ	After TCZ	Before TCZ	After TCZ	Improved
1	M	2	9.2	56	5	0	11500	6700	3	0.1	60	14	3	1.63	12 (9)	11 (7)	-2.5	-3.6	4	3	3
2	M	2.1	10.4	56	0	2	11800	5200	0.63	0	38	3	0.63	0.25	25 (20)	12 (7)	-1.5	-3.1	6	4	0
3	F	2.9	9.9	56	0	0	6300	4600	2.25	0	18	7	2.25	0	38 (24)	17 (11)	-6.6	-1.6	9	1	0
4	M	8.2	13.6	56	12	0	19000	4600	1.5	0	104	0	1.5	1	16 (12)	18 (12)	-4.4	-4.8	2	4	4
5	F	6.9	9.1	56	0	0	15100	4800	0.38	0	24	4	0.38	0	6 (4)	1 (1)	0.5	0.6	6	3	1
6	M	3.9	10	56	11	0	15400	7800	3	0	45	1	3	NA	20 (16)	12 (10)	-3.0	-7.4	7	2	1
7	M	2.8	3.4	56	4	0	13900	4900	1.88	0	48	2	1.88	0	6 (4)	0 (0)	-1.9	-1.2	6	4	0
Total (Avr.)	F:2, M:5	4.1	9.4	56	4.6	0.3	13286	5514	1.81	0.01	48.1	4.4	1.81	0.48	17.6	10.1	-2.8	-3.0	40 (57%)	21 (30%)	9 (13%)

Values in parenthesis are Larsen score of weight-bearing joints (knees, hips and ankles).

CHAQ, Childhood Health Assessment Questionnaire; CRP, C reactive protein; ESR, erythrocyte sedimentation ratio; F, Female; M, Male; NA, not available; TCZ, tocilizumab; WBC, white cell count.



Figure 1 Improvement in damaged hip joints. (A) Before tocilizumab treatment (9.9 years old). Severe erosions, cysts and joint space narrowing are observed in bilateral hips. (B) Erosions, cysts and joint space narrowing show amelioration, and marked joint remodelling is observed in both hips at 56 months after tocilizumab treatment (14.5 years old). There is a localized growth abnormality (short neck).

to reach agreement in all cases. For statistical analysis, Student t test was used to assess the significance of differences in results before versus after treatment. Correlations were assessed using Spearman's rank correlation coefficient. A p value less than 0.05 was considered significant.

Mean active joint counts, laboratory data and the Childhood Health Assessment Questionnaire (CHAQ) value decreased significantly after tocilizumab treatment (table 1). Radiographic abnormalities had all decreased at the final follow-up, with the exception of growth abnormalities. Joint space narrowing, subchondral bone cysts and erosion improved after tocilizumab treatment from 42.9%, 12.9% and 21.4% to 30.7%, 1.4% and 0%, respectively ($p < 0.05$ for joint space narrowing and $p < 0.01$ for subchondral bone cyst and erosion). However, the frequency of localised growth abnormalities increased from 15.7% to 36.4% after tocilizumab treatment ($p < 0.01$). The total Larsen score decreased from 17.6 before tocilizumab treatment to 10.1 at the final follow-up ($p < 0.05$). Radiographic improvement was observed in 40 joints (57%) but worsened in 9 (13%). In joints with radiographic improvement, joint destruction (ie, joint space narrowing), subchondral bone cysts and erosion were all improved, with marked joint remodelling and amelioration of osteoporosis (figure 1). The Poznanski score did not change after tocilizumab treatment; however, it correlated significantly with the total Larsen score ($r = 0.58$, $p < 0.05$). There were two cases (1 and 4) with 7 joints that showed worsening (3 joints in case 1 and 4 in case 4). In these patients, the Poznanski score also worsened, and CHAQ did not show full recovery.

The present study showed marked radiographic improvement of damaged large joints in tocilizumab-treated systemic-onset JIA patients. Radiographic findings of joint destruction, such as joint space narrowing, subchondral bone cysts and erosion, all diminished after tocilizumab treatment, and osteoporosis showed marked amelioration. Moreover, damaged joints were remodelled, and improvement of radiographic findings was maintained for about 5 years. To our knowledge, the present study is the first to document radiographic improvement, maintained long-term, after tocilizumab therapy in damaged large joints of systemic-onset JIA patients.

The limitations of this study are small sample size and radiographic deterioration in some joints (13%), despite stabilisation of systemic inflammatory responses. Further studies with a larger number of patients are needed.

Yutaka Inaba,¹ Remi Ozawa,² Tomoyuki Imagawa,² Masaaki Mori,² Yoshinori Hara,² Takako Miyamae,² Chie Aoki,¹ Tomoyuki Saito,¹ Shumpei Yokota²

¹Department of Orthopaedic Surgery, Yokohama City University, Yokohama, Japan

²Department of Pediatrics, Yokohama City University, Yokohama, Japan

Correspondence to Yutaka Inaba, Department of Orthopaedic Surgery, Yokohama City University, 3-9 Fukuura, Kanazawa-ku, Yokohama 236-0004, Japan; yute0131@med.yokohama-cu.ac.jp

Competing interests None.

Patient consent Obtained.

Ethics approval All participants provided written informed consent, and this study was approved by the Institutional Review Board of Yokohama City University, Yokohama, Japan.

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Contributors All the authors contributed to the work described in the paper and all take responsibility for it. YI, RO and CA performed radiographic evaluation before and after tocilizumab treatment. TI, MM, YH and TM examined all the patients and carried out the clinical data collection and analysis. TS and SY formulated the study design. All authors have read and approved the final manuscript.

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POSTERIOR SHEAR FORCE AND POSTERIOR TIBIAL DISPLACEMENT USING A SLING BRIDGE IN PATIENTS WITH POSTERIOR CRUCIATE LIGAMENT INSUFFICIENCY

T Sakai¹, M Koyanagi², K Nakata³, H Fujisaki⁴, T Yamagata⁴, K Hidaka⁵, Y Suzuki⁶, N Nakamura¹ ¹*Department of Rehabilitation Science, Osaka Health Science University, Osaka, Japan;* ²*Department of Physical Therapy, Osaka Electro-Communication University, Osaka, Japan;* ³*Department of Orthopaedics, Osaka University Graduate School of Medicine, Osaka, Japan;* ⁴*Department of Electrical and Electronic Engineering, Osaka Electro-Communication University Graduate school, Osaka, Japan;* ⁵*Department of Medical Technology, Division of Radiology, Osaka University Hospital, Osaka, Japan;* ⁶*Kibikogen Rehabilitation Center For Employment Injuries, Okayama, Japan*

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Background Rehabilitation training of hamstring muscle with deep knee flexion should be restricted following the posterior cruciate ligament (PCL) reconstruction because it stresses the PCL graft. To perform rehabilitation training of the hamstring muscle without the stress to the PCL, we have developed a sling bridge exercise (SB), which is a hamstring exercise with a sling at a lower leg to lift the buttocks in a supine position. Our hypothesis is that anterior traction force generated by a sling decrease strain on the PCL during SB.

Objective To analyze posterior shear force and amount of posterior tibial displacement by the SB and compare with those by the conventional bridge (CB) exercise.

Design Quasi-experimental study.

Setting Controlled laboratory research.

Participants Five healthy male volunteers and one patient with PCL insufficiency.

Intervention Position of physical segments and force on floor were analyzed by a 3D motion capture system and force plate. Posterior tibial displacement was measured by lateral XP view of the knee during the exercises.

Main outcome measurements Posterior shear force of the knee was calculated by using a biomechanical musculoskeletal model. Posterior tibial displacement was measured by digitised XP.

Results Posterior shear force of the healthy volunteers was 849.0 ± 322.5 N during CB and 360.6 ± 75.5 N during SB. In a patient with the PCL insufficiency, side-to side difference in posterior tibial displacement by SB (1.2 mm) was smaller than that of CB (3.3 mm).

Conclusion The SB hamstring exercise causes less posterior shear force and resulted in less posterior tibial displacement than a CB exercise. Therefore, a sling hamstring exercise is safer than a CB exercise in rehabilitation training for the patients with PCL reconstruction of the knee.



Posterior shear force and posterior tibial displacement using a sling bridge in patients with posterior cruciate ligament insufficiency

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Triple-bundle ACL grafts evaluated by second-look arthroscopy

Yoshinari Tanaka · Konsei Shino · Shuji Horibe ·
Norimasa Nakamura · Shigeto Nakagawa · Tatsuo Mae ·
Hidenori Otsubo · Tomoyuki Suzuki · Ken Nakata

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Abstract

Purpose The purpose of this study was to evaluate the morphology of transplanted triple-bundle anterior cruciate ligament (ACL) grafts by second-look arthroscopy.

Methods The subjects were 41 patients with a mean age of 25.5 ± 8.5 years who underwent second-look arthroscopy at between 6 and 22 months after the anatomical triple-bundle ACL reconstruction using semitendinosus tendon autograft. Lachman test was negative in 38 knees and mildly positive with a firm endpoint in 3 knees. Arthroscopic evaluation of grafts was performed for the anteromedial graft (AM), the intermediate graft (IM), and the posterolateral graft (PL), focusing on tension and graft damage.

Results All grafts showed “fan-out” shape approaching the tibial attachment, which looked closer to the natural ACL compared to the double-bundle grafts. As to graft tension, 93% of AM, 90% of IM, and 88% of PL grafts were evaluated as taut, respectively. As to graft damage, there was no apparent rupture in the AM and IM grafts, while complete or substantial rupture was observed in 10% of PL grafts around the femoral tunnel aperture. The incidence of graft rupture in PL grafts was significantly greater than those in the AM and IM grafts. As to synovial coverage, 76% of AM, 78% of IM, and 59% of PL grafts were evaluated as “Good,” while 41% of PL grafts were not fully covered with synovium. All of the synovial defects were observed around the femoral tunnel aperture.

Conclusion The morphology of the triple-bundle grafts resembled that of the natural ACL, while complete or substantial rupture was observed in 10% of the PL grafts.

Level of evidence Study of case series with no comparison group, Level IV.

Y. Tanaka (✉) · S. Horibe
Department of Sports Orthopaedics, Osaka Rosai Hospital,
1179-3 Nagasone-cho, Kita-ku, Sakai, Osaka 583-8555, Japan
e-mail: yoshi-tanaka@iris.eonet.ne.jp

K. Shino
Faculty of Comprehensive Rehabilitation, Osaka Prefecture
University, Sakai, Japan

N. Nakamura
Institute for Medical Science in Sports, Osaka Health Science
University, Kumatori, Japan

S. Nakagawa
Department of Sports Orthopaedics, Yukioka Hospital,
Osaka, Japan

H. Otsubo · T. Suzuki
Department of Orthopaedics, Sapporo Medical University,
Sapporo, Japan

T. Mae · K. Nakata
Department of Orthopaedic Surgery, Osaka University Graduate
School of Medicine, Osaka University, Osaka, Japan

Keywords Triple-bundle ACL reconstruction ·
Semitendinosus tendon autograft · Second-look
arthroscopy · Graft morphology

Introduction

Anterior cruciate ligament (ACL) reconstruction using hamstring tendon has become popular because of less donor site morbidity [4, 6, 14]. In addition, recent improvement in operative technique has made it possible to perform anatomical double-bundle ACL reconstruction, superior in biomechanical performances [13, 26] to the traditional Rosenberg's 1 or 2 femoral sockets (“bi-socket”) procedure. This could have resulted in more

favorable clinical results [15] while the results remain controversial [19, 20].

According to the previous reports on the functional anatomy of the ACL, it could be divided into three bundles: the anteromedial (AM), the intermediate (IM), and the posterolateral (PL) [1, 17]. Additionally, it is well known that the natural ACL forms a crescent-shaped footprint on the femur and a triangular one on the tibia. Furthermore, in the double-bundle ACL reconstruction, the authors have found no graft implanted into the anterolateral portion of the tibial footprint (Fig. 1a). To closely mimic this normal structure and restore normal knee function, we have developed the triple-bundle ACL reconstruction [23]. As previously described, we have divided the “anteromedial graft” in the anatomical double-bundle ACL reconstruction into further two bundles (the AM and the IM grafts) to form a triangular shape in the tibial attachment (Fig. 1b) [23]. The aim of this study was to evaluate the morphology of the transplanted triple-bundle grafts by second-look arthroscopy.

Materials and methods

Between 2004 and 2006, the anatomical triple-bundle ACL reconstruction using semitendinosus tendon autograft was performed on 172 knees. Of those, second-look arthroscopy was performed on 42 knees in 42 patients who gave their informed consent. It has been our policy to recommend patients to undergo second-look arthroscopy as well as hardware removal. As the clinical record of one patient was incomplete, the other 41 patients were included in this study. Patients included 16 men and 25 women, with a mean age of 25.5 ± 8.5 years. The mean duration of follow-up was 11.4 ± 3.9 months. At the time of second-look arthroscopy, none of the patients complained of subjective instability. Lachman test was negative in 38 knees and mildly positive with a firm endpoint in 3 knees. Positive pivot shift test of +1 was found in one patient. The mean side-to-side difference with the KT-1000 arthrometer at maximum manual force was 0.7 ± 1.2 mm (Fig. 2).

Fig. 1 Arthroscopic appearance of transplanted grafts in the left knee at the primary reconstruction. **a** Double-bundle reconstruction. Note the graft defect in the anterolateral portion of the tibial footprint (*arrowheads*). **b** Triple-bundle reconstruction. The intermediate graft occupies the anterolateral space (*arrows*)

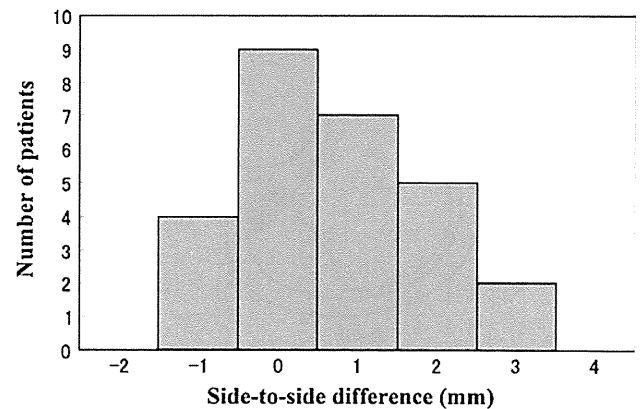
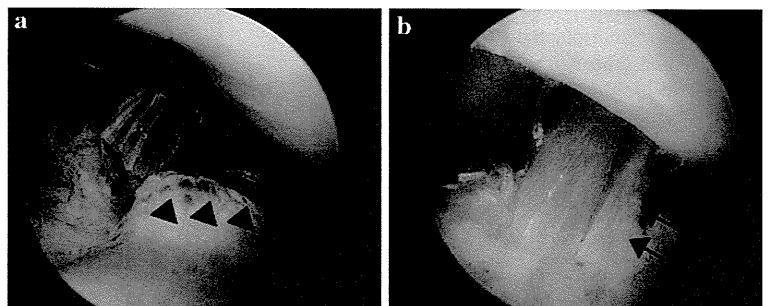


Fig. 2 The distribution of side-to-side differences in anterior laxity measured with the KT-1000 in 27 patients and the average value was 0.7 ± 1.2 mm

Surgical procedure

The procedure of triple-bundle ACL reconstruction was previously described in 2005 [23]. Briefly, two 2.4-mm guide pins were inserted to the points between the Resident’s ridge and the posterior margin of the notch at 2, 3 o’clock for the left or at 9, 10 o’clock for the right knee using the anterolateral entry femoral aimer (Smith & Nephew Endoscopy, MA). For the tibia, three parallel guide pins were inserted using the offset parallel pin guide (Smith & Nephew Endoscopy, MA). Then, each wire was overdrilled with a drill bit of appropriate diameter (5–6 mm in diameter) (Fig. 3). After introducing the anteromedial and posterolateral grafts into each femoral tunnel, both the grafts were fixed with Endo-button CLs (Smith and Nephew Endoscopy, MA). For the tibial fixation, two double-spike plates (DSP; MEIRA Corp., Nagoya, JAPAN; US Patent No. 6117,139,21) and the tensioning boot were used as described [22, 23]. After the posterolateral graft and the two anterior graft sutures (the AM and IM) were tied to the DSPs, the tensioning sutures, which were applied to the bottom of the DSPs, were connected to the tensioners. The tensioners were mounted on the tensioning boot, which was affixed to the

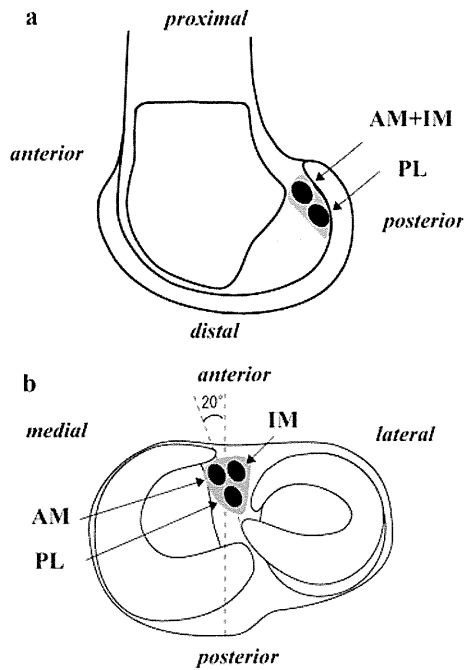


Fig. 3 Tunnel locations in the original ACL footprints (**a** femoral; **b** tibial): *AM* anteromedial, *IM* intermediate, *PL* posterolateral tunnel

tibia with a bandage. The 0.5 MPa of stress (approximately 10–15 N for each graft) was applied as the initial tension, and the knee was moved through a passive flexion and extension movement several times. After retighten tensioning suture by repetitive manual pulling to remove

stress relaxation, each graft was fixed at 15–20° of knee flexion with DSPs and cancellous screws.

Postoperative rehabilitation

Postoperatively, the knee was immobilized with a brace for a week. Partial weight bearing was allowed at 3 weeks, followed by full weight bearing at 5 weeks. Jogging was allowed at 3 months and running was permitted at 4 months, followed by return to previous sports activity at 6–9 months.

Arthroscopic evaluation of the transplanted grafts

Arthroscopic evaluation of the grafts was performed by meticulous probing as described, focusing on tension and graft damage [10, 18, 25]. Tension of the graft was classified as taut or lax by probing at 20–90° of knee flexion. The grafts as tense as normal ACL throughout the range of motion were evaluated as taut, while those with grafts looser than the normal were evaluated as lax (Fig. 4). Graft damage was evaluated in each bundle and classified according to whether there was a substantial tear (Fig. 5). In addition, synovial coverage of the grafts was classified into the following 3 categories: “good,” when the whole length of the graft was covered with the synovium; “fair,” when more than 50% of the entire surface of the graft was

Fig. 4 Arthroscopic classification of transplanted grafts based on graft tension. **a** Taut AM, IM, and PL grafts. **b** Lax AM, IM, and PL grafts

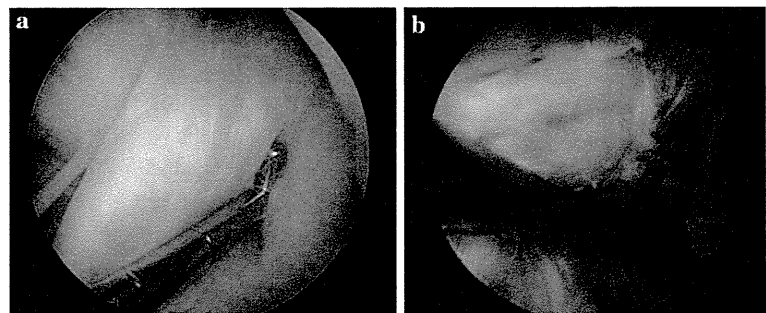


Fig. 5 Arthroscopic classification of transplanted grafts based on graft damage. **a** No rupture in all the grafts. **b** Complete rupture in the PL graft (arrows)

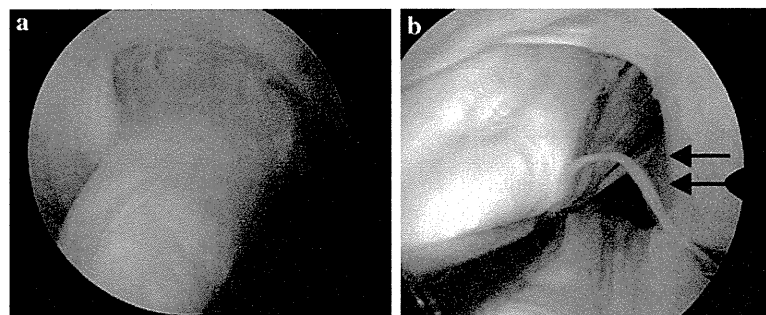
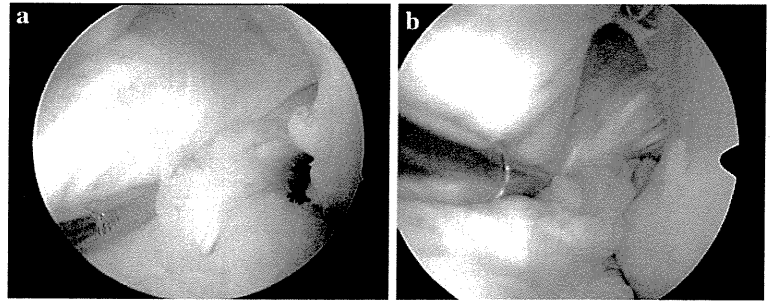


Fig. 6 Arthroscopic classification of transplanted grafts based on synovial coverage over the grafts. **a** “Good” synovial coverage in the AM and “Fair” in the IM. **b** “Poor” synovial coverage in the PL around the femoral tunnel aperture



covered with synovium; and “poor,” when less than 50% of the graft showed synovial coverage (Fig. 6).

Correlation between morphological defects and clinical results

We examined whether these morphological defects in the PL grafts, including graft damage and incomplete synovial coverage, have an effect on clinical results at 2 years postoperatively.

Statistical analysis

The chi-square test and the Mann–Whitney U test were used for statistical analysis; a difference of $P < 0.05$ was considered significant.

Results

Graft morphology

All of the grafts showed more broad or “fan-out” shape approaching the tibial attachment (Fig. 7a). As to graft tension, 93% of the AM, 90% of the IM, and 88% of PL grafts were evaluated as taut, respectively. Significant

differences in graft tension were not found among the three bundles (Table 1).

In terms of graft damage, there was no apparent rupture in the AM and IM grafts, while complete or substantial rupture was observed in 10% of the PL grafts around the femoral tunnel aperture (Fig. 5b). There was a significant difference in the incidence of graft damage among the three bundles ($P < 0.05$) (Table 1).

As to synovial coverage in the AM, thirty one grafts (76%) were evaluated as “Good,” while five other grafts (12%) were evaluated as “Fair” and five (12%) as “Poor”. In the IM grafts, 32 grafts (78%) were evaluated as “Good,” five (12%) as “Fair,” and four (10%) as “Poor”. As to the PL, twenty-four grafts (59%) were evaluated as “Good,” ten (24%) as “Fair,” and seven (17%) as “Poor,” respectively (Table 1). As a result, 41% of the PL grafts were not fully covered with synovium, while significant differences in the condition of synovial coverage were not found among the three bundles. In these cases, all of the synovial defects were observed around the femoral tunnel aperture, showing poor graft-tunnel integration (Fig. 6b).

Correlation between morphology of the PL graft and clinical results

After the arthroscopic evaluation, 22 of the patients could be followed up for 2 years after the reconstruction postoperatively and directly examined the correlation between

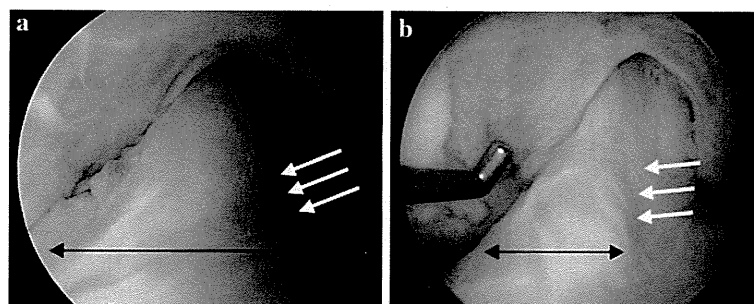


Fig. 7 Arthroscopic views of the multi-bundle ACL grafts. **a** A triple-bundle graft. Note the “fan-out” morphology approaching to the tibial attachment (*double-headed arrows*). **b** A double-bundle

graft. Its anterior portion around the tibial attachment looks narrower (*double-headed arrows*). The *white arrows* show boundary between the anterior portion and the posterolateral of the graft

Table 1 Arthroscopic morphology of each graft

	Tension		Graft damage		Synovial coverage		
	Taut	Lax	–	+	Good	Fair	Poor
AM graft	38 (93%)	3 (7%)	41 (100%)	0 (0%)	31 (76%)	5 (12%)	5 (12%)
IM graft	37 (90%)	4 (10%)	41 (100%)	0 (0%)	32 (78%)	5 (12%)	4 (10%)
PL graft	36 (88%)	5 (12%)	37 (90%)	4 (10%)	24 (59%)	10 (24%)	7 (17%)
<i>P</i> value	NS		0.016		NS		

morphology of the PL graft and clinical results among them.

According to IKDC subjective evaluation, 14 patients (64%) were graded as “normal” and the other eight patients (36%) as “nearly normal”. There was no obvious deterioration throughout the follow-up period in the grade of Lachman test and pivot shift test in all of them. While three had showed apparent damage in the PL at the second-look arthroscopy, it did not make significant differences in the results of a subjective evaluation, Lachman test, pivot shift test, or KT measurement (Table 2). In terms of the synovial coverage of the PL, although those with incomplete synovial coverage at second-look arthroscopy revealed less favorable results in the subjective evaluation than those with complete coverage, no significant difference was found (Table 3). Similarly, the incomplete synovial coverage has not yet led to inferior results in Lachman and pivot shift tests at least 2 years postoperatively (Table 3).

Table 2 Correlation between graft damage of the PL graft and clinical results

	PL graft damage		<i>P</i> value
	– (<i>n</i> = 19)	+ (<i>n</i> = 3)	
IKDC subjective evaluation			NS
A (normal)	12	2	
B (nearly normal)	7	1	
C (abnormal)	0	0	
D (severely abnormal)	0	0	
Lachman test			NS
Normal	18	3	
1+	1	0	
2+	0	0	
Pivot shift test			NS
Negative	18	3	
Gliding	1	0	
Positive	0	0	
KT side-to-side difference (mm)	1.0 ± 1.3	0.0 ± 0.0	NS

Table 3 Correlation between synovial coverage of the PL graft and clinical results

	Synovial coverage		<i>P</i> value
	Good (<i>n</i> = 13)	Fair/poor (<i>n</i> = 9)	
IKDC subjective evaluation			NS
A (normal)	9	5	
B (nearly normal)	4	4	
C (abnormal)	0	0	
D (severely abnormal)	0	0	
Lachman test			NS
Normal	12	9	
1+	1	0	
2+	0	0	
Pivot shift test			NS
Negative	12	9	
Gliding	1	0	
Positive	0	0	
KT side-to-side difference (mm)	1.0 ± 1.5	0.7 ± 1.0	NS

Discussion

The most important finding of the present study was that the morphology of the triple-bundle grafts resembled that of the natural ACL. The natural ACL is composed of multiple fascicles, the basic unit of which is collagen. Each fascicle is composed of 3–20 subfasciculi that consist of groups of subfascicular unit [24]. It has been also described to be a complex anatomical structure where straight collagen bundles are formed by a complex network of interlacing fibrils [3]. To reproduce or mimic this multi-fascicular complex structure, current ACL reconstruction procedures are performed using multiple-bundle grafts.

Some authors have increasingly reported on an anatomical double-bundle ACL reconstruction, for it has several advantages to restore normal knee functions and to achieve successful results [13, 26]. Biomechanical study by Yagi et al. [26] revealed the importance of the anatomical reconstruction of both the anteromedial and the posterolateral bundle. Mae et al. [13] reported the study focusing on the laxity match pretension in which comparison was made in it between the anatomical double-bundle technique and the isometric bi-socket procedure and concluded that the former might restore the anterior stability more effectively than the latter.

In addition, it has been reported that the natural ACL consists of multiple bundles that share tensile force during knee motion [1, 2, 17]. Amis and Dawkins divided the ACL into three functional bundles (AM, IM, and PL bundles) and showed force distribution among these bundles [1]. The IM bundle shared approximately 30% of the